Data Evaluation Record (DER)

Chemical names	CAS number	PC code
Dicamba: diglycoamine (DGA) salt	104040-79-1 (DGA salt)	128931 (DGA salt)
Dicamba: dimethylamine (DMA) salt	2300-66-5 (DMA salt)	029802 (DMA salt)
Dicamba: acid	1918-00-9 (Dicamba acid)	029801 (Dicamba acid)

Study Citation:
MRID 50578901
Gavlick, W.K. 2016. Determination of a No Effect Crop Response as a Function of Dicamba Vapor Concentration in a Closed Dome System. Unpublished study prepared by Monsanto Company. Study Number REG-2016-0574.

Purpose of Review: Dicamba DGA field buffer distance evaluation; DP 448082

This study is a follow-up study to Gavlick (2016: MRID 49925703) in which the NOAEC was determined to be 17.7 ng/m^3 with the next highest concentration tested (539 ng/m^3) resulting in significant plant height reductions (*i.e.*, the lowest observed adverse effect concentration [LOAEC]. Based on results from MRID 49925703, there was a 30x difference between the NOAEC and the LOAEC. The purpose of this study was to refine results from MRID 49925703 by testing air concentrations over a narrower air concentration range between NOAEC and LOAEC previously reported from MRID 49925703 to determine a refined NOAEC.

Date of Review: 8/8/2018

Summary of Study Findings: In this study, the relationship between dicamba vapor concentration and plant response was studied in order to determine a refined no observed adverse effects concentration (NOAEC) previously determined in Gavlick (2016: MRID 49925703). A track sprayer was used to dose Petri dishes with a dicamba containing formulation. The Petri dishes were placed inside a closed dome containing four soybean indicator plants. The closed dome was placed inside a growth chamber and air was drawn out of the closed dome and through a PUF (polyurethane foam) based dicamba collection system for 24 hours. Any dicamba that was present in the air was trapped on the PUF. The dicamba was extracted from the PUF, and the resultant extract solution was analyzed for dicamba by liquid chromatography- mass spectrometry (LC-MS/MS). After exposure, the plants were removed from the closed dome and placed in a greenhouse where they were rated for visual response at 14 and 20 days after treatment (DAT) and plant height 20 DAT. No plant height effects to soybean plants were observed as a result of vapor-phase exposure to dicamba at concentrations of 138 ng/m^3 and below but effects were seen at concentrations of 238 ng/m^3 and above. Therefore, the refined NOAEC was determined to be 138 ng/m^3 and should supplant the previous NOAEC of 17.7 ng/m^3 reported in Gavlick (2016: MRID 49925703).

Overall, the study design of this follow-up study is the same as the first study with the exception that the growth stage of the plants differed at test initiation (V1 growth stage in the current study and V2 growth stage in the former study). In summary, soybean plants (*Glycine max*; variety AG2632) at the V1 growth stage at study initiation were exposed to various volatilized dicamba formulations in closed dome systems for 24 hours. The specific dicamba formulations tested are identified by treatment in **Table 1**. It appears that some dicamba formulations were combined within individual treatments to create a dicamba vapor exposure concentration series. Each treatment was replicated three times with four soybean plants per replicate. For each treatment and replicate, six petri dishes (90mm ID, glass) were sprayed with the specific dicamba formulation at a rate equivalent to 10 gallons product per acre and placed in a closed dome system with the soybean plants (petri dishes in the control were not sprayed). Each humidome (**Figure 1**) was connected to a vacuum pump that circulated air through the humidome, plastic tubing, and a polyurethane foam filter at a rate of two standard liters per minute for 24 hours (atmospheric conditions in the humidome were maintained at 85°F for 16 hours and 70°F for 8 hours with 40% relative humidity). Following the 24 hour exposure to dicamba vapor in the closed dome systems, the soybean plants were moved to a greenhouse for 21 days. Visual phytotoxic responses were evaluated on days 14 and 20 post-treatment and plant height measurement were taken on day 20 post-treatment. Also following the completion of the 24 hour exposure phase, the polyurethane foam filter was removed and the dicamba trapped by the filter was extracted using methanol and quantified using LC-MS.

Table 1. Dicamba treatments, weight percent dicamba acid, and test chamber mean measured dicamba acid concentrations

Treatment Number	(w/w) Composition	Mean Measured Dicamba Acid Concentration (ng/m^3)
1	Deionized water	<3.5
2	100% M1691 (1.2% ae)	31.2
3	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae)	70.6
4	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae)	120
5	95% M1691 (1.2% ae) & 5% Banvel® (1.2% ae)	138
6	75% M1691 (1.2% ae) & 25% Banvel® (1.2% ae)	238
7	75% M1691 (1.2% ae) & 25% Banvel® (1.2% ae)	484
8	75% M1691 (1.2% ae) & 25% Banvel® (1.2% ae)	537

M1691 active ingredient: dicamba DGA salt
Banvel® active ingredient: dicamba DMA salt

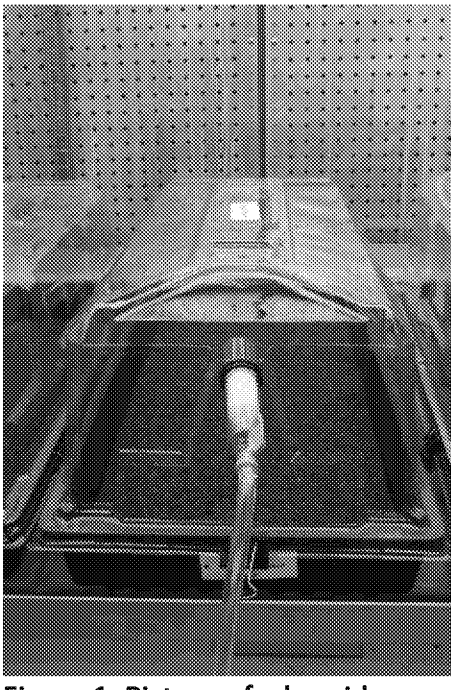

Figure 1. Picture of a humidome apparatus used in the study

Results:

Plant height was statistically significantly reduced compared to the control at vapor-phase exposure to dicamba at air concentrations of 238 ng/m^3 and above based on the study author's analysis (**Table 2**). No significant decrease in plant height was seen at the 138 ng/m^3 vapor-phase dicamba air concentration based on the study author's analysis, making this treatment concentration the study NOAEC.

Table 2. Mean Dicamba Exposure Concentrations and Mean Plant Height Across Three Replicates

Treatment Number	Mean Measured Dicamba Acid Concentration (ng/m^3)	Mean Plant height (cm)
1	<3.5	28.08
2	31.2	28.75
3	70.6	29.42
4	120	29.00
5	138	27.71
6	238	24.63*
7	484	21.08*
8	537	19.88*

*Height values with an asterisk are statistically significantly reduced compared to the control (treatment 1)

Plant response was assessed on a scale of 0 to 100 with 0 representing no visible plant response and 100 representing complete plant death. All of the Greenhouse Control plants (which were added after the test plants were treated) were assessed as having no visible plant response (rating of 0) at 14 and 20 DAT. This indicated that there were no environmental factors which would have caused a plant response. Treatments 1 through 6 produced slight to no noticeable effects at 20 days. Treatments 7 and 8 produced moderate effects at 20 days. A summary of the plant response data is found in Table 3.

Table 3. Visual Phytotoxic Response

	14 Day Visual Response %		20 Day Visual Response %	
Treatment Number	Mean	Standard Deviation	Mean	Standard Deviation
1	< 1	-----	0	------
2	3	6	<1	-----
3	7	4	5	4

4	11	5	10	8
5	19	10	11	8
6	25	14	23	17
7	42	13	38	11
8	52	12	43	14

Study Classification: While this study was not conducted per an EPA OCSPP guideline protocol (no such protocol exists), it was conducted in accordance with Good Laboratory Practice standards. The study is scientifically sound and classified as **Supplemental**, suitable for quantitative use in risk assessment.

Rationale for Use: The explicit purpose of this study was "to examine the relationship between dicamba vapor concentration and plant response to identify a refined no observed effect concentration (NOEC) that can be used to support the risk assessment for dicamba use on dicamba-tolerant crops." Analytical and biological results were obtained. The biological results indicate that soybean height is not significantly reduced compared to control plants following 24 hours of exposure (at 85°F for 16 hours and 70°F for 8 hours with 40% relative humidity) to vapor-phase dicamba at concentrations less than or equal to 138 ng/m^3 (*i.e.*, the total cumulative exposure concentration at the end of 24 hr time period); however, 24 hour exposure (at 85°F for 16 hours and 70°F for 8 hours with 40% relative humidity) to concentrations of vapor-phase dicamba greater than or equal to 238 ng/m^3 significantly reduced soybean height compared to control plants ($p<0.0001$).

Limitations of Study:

Only one concentration of dicamba DGA was tested in this study. Without multiple concentrations of the dicamba DGA formulation tested it is uncertain whether the amount of volatilized dicamba linearly correlates with the amount of dicamba DGA applied. Further,

the influence of the atmospheric conditions of the test design (*i.e.*, temperature and relative humidity) on the amount of volatilized dicamba and subsequent entrapment in the polyurethane foam and on the observed phytotoxic and height response is uncertain.

Primary Reviewer: Brian D. Kiernan 8/8/2018

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Secondary Reviewer: Michael Lowit 9/6/18

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